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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ARBUTUS BIOPHARMA CORP. and GENEVANT SCIENCES GMBH, Plaintiffs, v. PFIZER INC. and BIONTECH SE, Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** *Document Filed Electronically* Jury Trial Demanded

Arbutus Biopharma Corp. ("Arbutus"), with its principal place of business at 701 Veterans Circle, Warminster, Pennsylvania, 18974, and Genevant Sciences GmbH ("Genevant") (collectively, "Plaintiffs"), with its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland, by and through their attorneys, bring this Complaint against Pfizer Inc. ("Pfizer"), with its principal place of business in New York City and significant operations in New Jersey,

and BioNTech SE ("BioNTech") (collectively, "Defendants"), with its principal place of business in Germany and its North American headquarters in Cambridge, Massachusetts, and allege as follows:

INTRODUCTION

1. Arbutus invented and was awarded numerous patents on the breakthrough lipid nanoparticle ("LNP") technologies needed to deliver messenger ribonucleic acid ("mRNA") therapeutics to human cells. Genevant, a world leader in nucleic acid drug delivery and development, licenses these patents from Arbutus.

2. When the world was thrust into a devastating pandemic and urgently needed LNP technologies to deliver an mRNA-based COVID-19 vaccine to cells in the body, the necessary LNP technologies had, fortunately, already been invented by Arbutus's scientists years before and stood ready for use. Defendants could not have accomplished the feat of creating and manufacturing a vaccine at a speed unprecedented in the history of medicine but for their use of Plaintiffs' existing and proven LNP technologies. Yet Defendants never paid Plaintiffs to use those technologies. And Defendants continue to knowingly use the technologies to make and sell the vaccine, amassing tens of billions of dollars in revenues. Plaintiffs have thus filed this case to obtain fair compensation for their inventions, without which the vaccine would not exist.

3. Defendants' vaccine works by delivering a synthetic mRNA to the body's cells. The biggest technological barrier to mRNA-based medicines is not the mRNA itself—BioNTech's CEO designed the mRNA over a weekend. The biggest barrier is instead how to *deliver* the mRNA to cells safely and effectively. As Pfizer's CEO Albert Bourla has explained, "[t]he whole mRNA [vaccine] platform is not how to build an mRNA molecule; ***that's the easy thing***." The hard thing

is "***how to make sure the mRNA molecule will go into your cells*** and give the instructions."[1] A Nobel Prize-winner has similarly explained that the key to RNA therapeutics was "***delivery, delivery, delivery***."[2]

4. The delivery problem had persisted for decades until a team of Arbutus scientists, many now at Genevant companies, developed and refined technologies that solved the problem, for which they were awarded many patents. Their solution involved microscopic particles, built from four carefully-selected types of fat-like molecules, that are stable enough to shelter and protect fragile ribonucleic acid ("RNA") molecules on a voyage through the human body to a target cell, and then through the target cell's membrane, before finally releasing the RNA. These particles are called lipid nanoparticles and their invention was widely recognized as a major achievement that is essential for mRNA vaccines.

5. Arbutus also developed the technologies needed to manufacture these LNPs. Before Arbutus's scientists tackled the manufacturing challenges, methods of manufacturing LNPs for RNA employed harsh conditions that would damage the RNA that the LNPs were supposed to protect. Arbutus's scientists developed new, elegant manufacturing methods that preserved the RNA and allowed for it to reach target cells in an undamaged state. Their solution used what is called a T-connector to mix together flows of lipids and dissolved RNAs in a process that ensures the RNA is both encapsulated and protected during the formulation process.

6. Defendants have long recognized the value of Plaintiffs' LNP technologies and patent rights. For example, in 2018, BioNTech paid for a license to use the technologies in a

[1] Nathan Vardi, *Covid's Forgotten Hero: The Untold Story Of The Scientist Whose Breakthrough Made The Vaccines Possible*, Forbes, Aug. 17, 2021 (https://tinyurl.com/86ud83kj).
[2] Erika Check, *RNA to the Rescue?*, Nature, 425:10-12 (2003) (www.nature.com/articles/425010a).

contract that described Genevant's platform as "the best lipid nanoparticle technology." The license only permitted BioNTech to use the technology in specific cancer and rare liver disease treatments and did not extend to uses for infectious diseases like COVID-19. Pfizer, on information and belief, has long known about that license and Plaintiffs' patents. Yet neither BioNTech nor Pfizer asked for a license to use Plaintiffs' LNP technologies in a COVID-19 vaccine. They just used the technologies without paying for them—keeping for themselves tens of billions in revenue that would never have existed were it not for Plaintiffs' innovation.

7. Plaintiffs have licensed their technologies to many companies and would have granted a license to Defendants on reasonable terms for use in a COVID-19 vaccine. Indeed, the parties engaged in licensing discussions that unfortunately failed to result in a settlement. Plaintiffs have therefore been left no choice but to file this lawsuit to seek fair compensation in the form of a reasonable royalty for Defendants' unlicensed use of Plaintiffs' patents.

NATURE OF THE ACTION

8. This is a civil action by Plaintiffs against Defendants under the patent laws of the United States, 35 U.S.C. § 101 *et seq*., seeking damages for Defendants' infringing manufacture, use, sale, offer for sale, and/or importation of their COVID-19 vaccine and any COVID-19 mRNA-LNP vaccine products, including: pediatric doses; booster doses; supplemental doses; reformulations; boosters or re-vaccinations; variant-specific formulations; bivalent formulations; and the products known or marketed as Pfizer-BioNTech SE (BioNTech) COVID-19 vaccine, Comirnaty, Tozinameran, BNT162b2, or PF-07302048 (collectively, the "Accused Product" or "Defendants' vaccine").

9. Defendants' manufacture, use, sale, offer to sell, and/or importation of the Accused Product directly and/or indirectly infringes or will infringe, or actively induces or will actively induce infringement of, one or more valid enforceable claims of, and Plaintiffs' rights arising

under, the following patents relating to nucleic acid-lipid particles, compositions thereof, their manufacture, and/or their use to deliver mRNA and/or other nucleic acid-based medicines: U.S. Patent Nos. 9,504,651 (Exhibit A); 8,492,359 (Exhibit B); 11,141,378 (Exhibit C); 11,298,320 (Exhibit D); and 11,318,098 (Exhibit E) (collectively, the "Asserted Patents"). At all relevant times, Arbutus owned the Asserted Patents and licensed exclusive rights to sublicense, practice, and sue for infringement of them to Genevant in certain fields of use that include the vaccine application at issue in this Complaint, with certain exceptions not relevant here (hereinafter, Genevant's "Exclusive Rights").

PARTIES

10. Plaintiff Arbutus Biopharma Corporation is a Canadian corporation with its principal place of business at 701 Veterans Circle, Warminster, Pennsylvania, 18974. The company's research and development efforts include discovering, developing, and commercializing a cure for chronic hepatitis B virus, as well as drug discovery and development for treating coronaviruses, including SARS-CoV-2, which causes COVID-19.

11. Plaintiff Genevant Sciences GmbH is a Swiss company with its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland. Together with its affiliated companies, it maintains an office in Cambridge, Massachusetts, and Vancouver, British Columbia. Genevant is a technology-focused nucleic acid delivery solutions company with cutting-edge LNP platforms. Genevant owns or licenses the industry's most important LNP intellectual property—that of Arbutus—and has decades of experience and expertise in nucleic acid drug delivery and development. Genevant's mission is to utilize its LNP and other technologies to deliver innovative new medicines that use mRNA or other nucleic acids.

12. Defendant Pfizer is a Delaware corporation with its principal place of business in New York City and significant operations in New Jersey. According to Pfizer's 2022 annual

report, Pfizer's global supply "leadership teams" are located primarily in New York City and New Jersey.

13. Defendant BioNTech SE is a German corporation with its principal place of business in Germany and its North American headquarters in Cambridge, Massachusetts.

14. Pfizer and BioNTech are and have been operating jointly and as agents of one another as to Defendants' vaccine and share equally in profits from sales of the vaccine. For example:

- A March 17, 2020, Collaboration Agreement reflects Pfizer and BioNTech's agreement to engage in "collaborative research and development" to develop and launch a Covid-19 vaccine "in all countries of the Territory," and their "wish that Pfizer Commercialize[] the Product in all countries of the Territory," where (i) "Commercialize" is defined as "market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize a compound or product," and (ii) "Territory" is defined to include the United States.

- Pfizer's 2022 annual report, published on or about February 23, 2023, states that Pfizer and BioNTech have been "collaborat[ing]" to "jointly develop[] and commercialize[]" the vaccine; discusses "Comirnaty-related manufacturing activities performed [by Pfizer] on behalf of BioNTech"; and explains that Pfizer and BioNTech "equally share the costs of development" and "share gross profits equally from commercialization." Similarly, Pfizer and BioNTech's press releases have stated that "BioNTech is the Marketing Authorization Holder [for the vaccine]… and the holder of emergency use authorizations … in the United States (jointly with Pfizer)."

- In a Complaint filed July 25, 2022, Pfizer and BioNTech alleged that they "partnered together, and continue to work together" on the vaccine; "partnered together to develop, manufacture, and secure regulatory approval" of the vaccine, including as to "clinical testing [and] distribution"; and "agreed to share the costs of developing" the vaccine. The Complaint also alleges that "Pfizer, on behalf of itself and BioNTech, submitted clinical trial data as part of an Emergency Use Authorization ('EUA') request to the FDA for administering the Pfizer-BioNTech COVID-19 vaccine…."[3]

[3] Complaint, *BioNTech SE, BioNTech Manufacturing GMBH, and Pfizer Inc. v. Curevac AG*, Case No. 1:22-cv-11202 (D. Mass. July 25, 2022) at ⁋⁋ 1, 2, 48, 49, 55.

JURISDICTION AND VENUE

A. Subject Matter Jurisdiction

15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this is an action for infringement under the patent laws of the United States, Title 35 of the United States Code.

B. Personal Jurisdiction

16. This Court has personal jurisdiction over Pfizer because it maintains a regular and established place of business in this District.

17. This Court has personal jurisdiction over both Pfizer and BioNTech because they transact business relating to Plaintiffs' claims in this District, engage in systematic and continuous business contacts here, and have purposefully availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being haled into court here.

18. Among other things, Pfizer and BioNTech operate jointly and/or as agents of one another to develop, manufacture, import, market, distribute, offer to sell, and/or sell the Accused Product in the State of New Jersey and throughout the United States, for use in the State of New Jersey and throughout the United States. Directly or through others, Pfizer and BioNTech make, use, induce others to use, offer for sale, and/or sell the Accused Product within the United States, and/or import the same into the United States, including into the District of New Jersey. They have also contracted with one another with the purpose and intent of inducing and participating in sales of the Accused Product in the United States, including in this State and District.

19. For example, on December 11, 2020, Defendants received Emergency Use Authorization ("EUA") from the United States Food and Drug Administration ("FDA") for Defendants' vaccine to be distributed and administered to people 16 years of age and older throughout the United States, including in the District of New Jersey, and, on August 23, 2021,

the FDA approved Defendants' Biologics License Application ("BLA") for the vaccine. Upon information and belief, as of April 2, 2023, more than 11.9 million doses of Defendants' vaccine have been administered in the State of New Jersey.[4] Therefore, Pfizer and BioNTech transact business within New Jersey relating to Plaintiffs' claims and have engaged in systematic and continuous business contacts here.

20. For the above reasons, there is nothing unreasonable or fundamentally unfair about requiring Pfizer and BioNTech to litigate this action in this District, and the Court has personal jurisdiction over them here.

C. Venue

21. Venue is proper in this District as to Pfizer pursuant to 28 U.S.C. § 1400(b) because Pfizer has committed acts of infringement in this District and has a regular and established place of business in this District. Among other things, Pfizer has committed acts of infringement in this District by making, using, selling, and/or offering for sale in this District the Accused Product and inducing others to use the Accused Product in this District. Moreover, Pfizer has a campus in this District, where leadership teams are located.

22. Venue is proper in this District as to BioNTech pursuant to 28 U.S.C. §§ 1400 and 1391 because it is subject to personal jurisdiction here.

BACKGROUND

A. Nucleic Acids

23. Defendants' vaccine belongs to a new class of medicines that delivers nucleic acids, such as mRNA, into the cells of the body to treat diseases or, in the case of Defendants' vaccine, to trigger an immune response to protect a person from future infection.

[4] https://www.nj.gov/health/cd/topics/covid2019_dashboard.shtml.

24. Nucleic acids are molecules that encode the genetic information essential to sustain all forms of life. One type of nucleic acid is deoxyribonucleic acid, or "DNA." Every human (except identical twins) has a unique set of genetic information in the "genes" (composed of DNA) within his or her chromosomes. Among other things, these genes spell out the instructions for producing proteins that make human cells and bodies function.

25. In order to make the protein encoded by a particular gene, cells first convert the genetic code in the gene's DNA into another type of nucleic acid known as messenger ribonucleic acid, or "mRNA." mRNA is effectively a copy of the portion of DNA that the cell's protein-making machinery uses as a blueprint to assemble the protein encoded by the gene.

B. How Vaccines Work

26. A virus is typically a small packet of DNA or RNA. If a virus enters a living host cell—for example, after being ingested, transmitted through bodily fluids, or inhaled through a person's mouth or nose—the virus's DNA or RNA hijacks the cell's machinery and instructs the cell to make copies of the virus. These copies, often numbering into the millions, leave the infected cell and enter other cells where the process repeats. Infected cells can be damaged or die while hosting the virus. Left unchecked, the host organism itself can die.

27. Although vaccines targeting viruses may have varying mechanisms of action, they traditionally work by injecting into the body a weakened or inactive form of the virus that is unable to cause infection but retains features of the infectious virus and can teach the immune system to recognize and attack the infectious virus if it invades in the future. These vaccines take tremendous amounts of time to develop and bring to patients due to the extensive amount of work needed to target specific infectious agents, associated regulatory hurdles, and other factors.

28. In a 2021 essay, Pfizer's CEO observed that "the typical vaccine development program can take up to 10 years and cost anywhere from $1 billion to more than $2 billion,"

including because "[t]raditionally, making a vaccine starts with growing weakened forms of the virus, which can take months."[5]

29. Thus, scientists began experimenting with a new, mRNA-based approach. Fundamentally, the proposed mRNA vaccines would work the same way as any other vaccine—exposing people to a piece of a virus or pathogen so as to trigger the immune system and induce adaptive immunity. However, with an mRNA vaccine, the immune system would not be triggered by a piece of virus or pathogen manufactured in a laboratory, as with older vaccines. Instead, the trigger would be manufactured in and by a person's own cells.

30. A major advantage of mRNA-based vaccines, if they could be made to work, was that they could be used with any mRNA. Rather than requiring years of development as with traditional vaccines, it was envisioned that the relevant mRNA could be identified and generated using existing technology, inserted into a general-use delivery mechanism, and made ready to inject into people, all in the space of days or weeks.

C. Challenges for RNA-Based Medicines and Arbutus's Pioneering Solutions

31. Vaccines and other medicines using RNA technologies are an emerging frontier with the potential to revolutionize medicine. RNA-based medicines can employ a type of RNA called small interfering RNA ("siRNA") to treat certain diseases by interfering with the expression of unwanted proteins to reduce the amounts produced—a process called RNA interference ("RNAi"). RNA-based medicines also can employ mRNA to cause or increase the production of certain proteins. mRNA vaccines, for example, can cause cells to express a protein (or a piece of a protein) that is part of a particular virus or that is found on a particular tumor. The presence of

[5] Albert Bourla, *The CEO of Pfizer on Developing a Vaccine in Record Time*, Harvard Bus. Rev. Magazine, May-June 2021 (https://hbr.org/2021/05/the-ceo-of-pfizer-on-developing-a-vaccine-in-record-time).

that protein (or piece of a protein) teaches the body's immune system to recognize it if it is encountered in the future and destroy it.

32. RNA-based medicines hold great promise for addressing many previously intractable diseases, including viruses like COVID-19 that cause or threaten global pandemics.

33. Despite their promise, however, RNA-based medicines were difficult to develop. By their nature, RNA molecules are fragile. Without adequate protection, RNA molecules are susceptible to degradation in the body; moreover, if and when RNA molecules get to a cell, they cannot cross the cell membrane to enter the cell.

34. For decades, the need for an effective delivery technology had been the most significant challenge in the development of RNA-based medicines. In particular, without the means to protect mRNA and facilitate its entry into target cells, mRNA-based vaccines and other medicines have been ineffective.

35. Dr. Katalin Karikó, former BioNTech Senior Vice President and lead vaccine development scientist, was among the scientists who recognized the significance of the delivery problem. One author quotes Dr. Karikó, speaking in regard to an unsuccessful effort in the years after 2005 to obtain lipids that she believed might be useful in delivering mRNA to human cells, as follows: "I was close to getting on my knees…. It was my lowest moment."[6]

36. For a long time, the "delivery problem" appeared unsolvable. Indeed, although nucleic acid vaccine development had initially attracted optimism, enthusiasm, and research funding, those trends reversed. As explained in a feature in *Nature*, "in the 1990s and for most of the 2000s, nearly every vaccine company that considered working on mRNA opted to invest its resources elsewhere," because "mRNA was seen as too unstable and expensive to be used as a

[6] Gregory Zuckerman, A SHOT TO SAVE THE WORLD (2021) at 82.

drug or a vaccine."[7] Companies that abandoned the field included one of the world's largest vaccine developers, which according to the same feature in *Nature* "evaluated the mRNA technology in mice with the aim of creating an influenza vaccine, but then abandoned that approach" because, in the words of a scientist who worked on the project, "'[t]he cost and feasibility of manufacturing just gave us pause.'" As another industry participant explained, "[t]here were many, many skeptics…. People used to say that if you looked at [mRNA] wrong it would fall apart."[8]

37. Functional RNA-based medicines eluded researchers until pioneering work by Arbutus scientists resulted in the discovery and development of the leading nucleic acid delivery technology in use today. Decades ago, a group of ambitious research scientists working at a predecessor company to Arbutus began to tackle the nucleic acid delivery problems that had long stymied the field. After years of tireless effort, these scientists solved these problems by developing both novel lipid formulations and innovative manufacturing processes. These scientists developed LNP technology that relies on fat-like molecules called lipids that encapsulate and protect nucleic acids like mRNA from degradation in the body and enable them to cross cell membranes. Once inside a cell, the LNP releases the nucleic acid it encapsulates so that, in the case of an mRNA vaccine for example, the nucleic acid can cause the cell to express the protein that the nucleic acid encodes.

38. The lipid components of the Arbutus technology include: structural lipids, such as phospholipids and cholesterol; "cationic" (positive charge-bearing) lipids, including "ionizable"

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[7] Elie Dolgin, *The Tangled History Of mRNA Vaccines*, Nature, Sept. 14, 2021 (https://www.nature.com/articles/d41586-021-02483-w).

[8] Ryan Cross, *Without These Lipid Shells, There Would Be No mRNA Vaccines For COVID-19,* Chem. & Engineering News, Mar. 6, 2021 (https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8).

lipids that are positive charge-bearing at certain pH levels; and conjugated lipids, such as lipids attached to a polyethyleneglycol ("PEG") polymer. Arbutus scientists discovered that nucleic acid-lipid particles combining particular lipid components could achieve much more effective delivery of nucleic acids through cell membranes and into cells.

39. Arbutus scientists spent almost two decades researching and developing their nucleic acid-lipid delivery technology. Their efforts led to the first FDA-approved RNA-LNP therapeutic, a drug called Onpattro®. Onpattro® is an RNAi treatment for a form of amyloidosis, a rare disease that causes certain proteins to accumulate in organs. The company that developed Onpattro®, Alnylam Pharmaceuticals, did so under an LNP license from Arbutus and received FDA approval in August 2018. Building on that success, Arbutus has licensed its LNP technology to other companies, and Genevant now has several ongoing LNP product development collaborations, some directed to COVID-19 and some directed to other diseases and disorders.

D. The United States Awards Patents Recognizing Arbutus's Innovations

40. In recognition of Arbutus's research and development efforts, the United States Patent and Trademark Office has granted several families of patents claiming nucleic acid-lipid particles and lipid vesicles, as well as compositions and methods of using and manufacturing them. Among those patents are the Asserted Patents:

a. U.S. Patent No. 9,504,651, "Lipid Compositions for Nucleic Acid Delivery," issued on November 29, 2016 (the "'651 Patent").

b. U.S. Patent No. 8,492,359, "Lipid Formulations for Nucleic Acid Delivery," issued on July 23, 2013 (the "'359 Patent").

c. U.S. Patent No. 11,141,378, "Lipid Formulations for Nucleic Acid Delivery," issued on October 12, 2021 (the "'378 Patent").

d. U.S. Patent No. 11,298,320, "Liposomal Apparatus and Manufacturing Methods," issued on April 12, 2022 (the "'320 Patent").

e. U.S. Patent No. 11,318,098, "Liposomal Apparatus and Manufacturing Methods," issued on May 3, 2022 (the "'098 Patent").

41. True and correct copies of the Asserted Patents are attached hereto as Exhibits A through E. All are valid and enforceable under United States patent laws. All are assigned to and owned by Arbutus, and, at all times since Arbutus and Genevant entered into a license agreement, Genevant has held Exclusive Rights to all of the Asserted Patents.

E. Defendants' Knowledge Of, And Background With, Arbutus's Patents

42. Defendants have been on actual notice of Arbutus's patents but nonetheless knowingly used Arbutus's technology in nucleic acid-based products and product candidates, including the Accused Product, without permission.

43. For example, on July 4, 2018, BioNTech signed a license agreement with Genevant in which BioNTech agreed to pay for the right to use Plaintiffs' LNP technology to develop and potentially commercialize certain cancer or rare liver disease treatments. The first page of the agreement confirms how critical Plaintiffs' LNP technology was: It not only notes Genevant's exclusive license "to certain intellectual property rights relating to RNA-based therapeutics enabled by lipid nanoparticle delivery technologies," but also states that "the Parties wish to jointly develop pharmaceutical products that combine the best mRNA payloads with ***the best lipid nanoparticle technology***"—a reference to Arbutus's technology.

44. The license agreement shows, among other things, that BioNTech knew about Arbutus's technology and patents, including the asserted '651 and '359 patents, at least as of 2018. It also shows that BioNTech knew it could not use Arbutus's technology without obtaining and paying for the right to do so. Indeed, BioNTech's annual reports for 2019, 2020, and 2021 referred to "many issued and pending patent filings that claim aspects of technologies that we may need for our mRNA product candidates or other product candidates, ***including patent filings that relate***

to relevant delivery technologies." On information and belief, that warning referred at least in part to patents at issue in this litigation.

45. On information and belief, Pfizer has received and reviewed a copy of the BioNTech-Genevant license agreement, including potentially (i) in the summer of 2018, as part of due diligence Pfizer conducted before signing a different contract with BioNTech, and (ii) in early 2020, as part of due diligence Pfizer conducted before agreeing to collaborate with BioNTech on Defendants' vaccine.

F. BioNTech Designs Its COVID-19 Vaccine with Unprecedented Speed, Aided by the Unauthorized Use of Arbutus's LNP Technology

46. Defendants have used and continue to use Arbutus's LNP technology without authority or license to do so and are willfully infringing the Asserted Patents jointly and/or as agents of one another.

47. On January 10, 2020, with the novel SARS-CoV-2 virus quickly spreading around the world, scientists identified the virus's complete genetic sequence and posted it on the internet. This public disclosure revealed the complete RNA sequence that encodes the virus's components, including its distinctive "spike protein." With that information in the public domain, researchers around the world were able to begin designing vaccines to target the virus.

48. On Friday, January 24, 2020, BioNTech's CEO read an article about the public health risks posed by COVID-19. According to statements he has given to the press, it was the first time he had focused on COVID-19 as a serious public health threat. ***Over the weekend, he designed several candidates for an mRNA vaccine***, targeting the virus that causes COVID-19 using the RNA sequence that had been published on the internet two weeks earlier. One of those candidates, designed to be inserted into a lipid nanoparticle for delivery into target cells, ultimately

became used in Defendants' vaccine. The vaccine was well on its way to clinical trials by the time of the first confirmed American death from COVID-19 in early February 2020.

49. Defendants' vaccine could not have been developed, much less on the fastest timeline in the history of vaccines, without Arbutus's proven and patented LNP delivery technology. Indeed, discussing Defendants' vaccine, Dr. Karikó has publicly stated that "***[t]he LNP is as important as the mRNA in the vaccine***."[9] Dr. Karikó has also been quoted as saying that "***a lot of credit goes to [Arbutus scientist and named inventor] Ian MacLachlan for the LNP***" used in the vaccine.[10]

50. Distribution and administration of the vaccine to persons in the United States and around the world (outside of clinical trials) began immediately after December 11, 2020, when the FDA granted Defendants an Emergency Use Authorization, and has continued through and after the FDA's August 23, 2021 approval to administer the vaccine to persons ages 16 and over.

51. Pfizer has asserted that it manufactured more than three billion doses of the vaccine in 2021 and expected to manufacture billions more doses by the end of 2022.[11] Pfizer also reported tens of billions in revenue from the vaccine in both 2021 and 2022.[12] Moreover, Pfizer's CEO Dr. Bourla has stated that those revenues actually ***understate*** what a "fair financial return" on the

[9] Katalin Karikó (@kkariko), Twitter (Aug. 17, 2021, 10:24 AM) (https://twitter.com/kkariko/status/1427637506913284101?ref_src=twsrc%5Etfw).

[10] Nathan Vardi, *Covid's Forgotten Hero: The Untold Story Of The Scientist Whose Breakthrough Made The Vaccines Possible*, Forbes, Aug. 17, 2021 (https://tinyurl.com/86ud83kj).

[11] Complaint, *BioNTech SE, BioNTech Manuf. GMBH, & Pfizer Inc. v. Curevac AG*, Case No. 1:22-cv-11202 (D. Mass. July 25, 2022) at ¶ 63.

[12] Pfizer 10K 2022 Annual Report (https://s28.q4cdn.com/781576035/files/doc_financials/2022/ar/PFE-2022-Form-10K-FINAL-(without-Exhibits).pdf).

vaccine would have been, including because Pfizer had set prices at a level intended to increase the value of Pfizer's public reputation.[13]

52. To date, hundreds of millions of doses of Defendants' vaccine have been administered to individuals throughout the United States.[14] Defendants' vaccine doses made in the United States and/or administered in the United States were distributed to hospitals, pharmacies, clinics, and numerous other entities for the benefit of individuals in the United States.

53. Millions more doses, including doses made in the United States, have been distributed and administered abroad, for the benefit of individuals outside the United States. In press releases and financial disclosures, Pfizer has stated that it shipped billions of doses to 181 countries. Several of those countries have confirmed that they received doses manufactured in the United States, including Canada, Mexico, and Australia. Moreover, reports indicate that Pfizer has also shipped U.S.-manufactured doses throughout Central and South America.

G. Genevant Attempts to Negotiate a License with Defendants

54. Plaintiffs tried to avoid the need to file this lawsuit.

55. Many companies have paid Plaintiffs for a license to use the breakthrough LNP technology at issue here, including several developing COVID-19 vaccines and several others with which Genevant has ongoing LNP product development collaborations. The research and development facilitated by these and other licenses has resulted in product candidates across a variety of conditions.

56. Genevant would have preferred to resolve Plaintiffs' dispute with Defendants with a mutually acceptable license. And Genevant has long sought to do just that. In proposing such a

[13] Albert Bourla, *MOONSHOT: INSIDE PFIZER'S NINE-MONTH RACE TO MAKE THE IMPOSSIBLE POSSIBLE* (2022) at 108.

[14] COVID-19 Vaccinations in the United States, CDC (https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total).

license, Genevant did not wish to minimize the importance of Defendants' extensive efforts to manufacture and distribute billions of doses of the vaccine in the midst of a global pandemic. Those efforts have been vitally important and have saved countless lives. Rather, Genevant sought only the fair and reasonable compensation to which Plaintiffs are entitled by law for their contributions to the vaccine—contributions that were the product of decades of pioneering work by Arbutus scientists, many now at Genevant companies, including during periods when it was uncertain whether mRNA vaccines could ultimately be made to work.

57. On November 23, 2020, Plaintiffs notified Defendants in writing that the manufacture, importation, offer for sale, sale, and/or use of the Accused Product may infringe the claims of at least the '651 Patent and the '359 Patent and offered to discuss the terms of a collaboration and/or license to further the parties' goal of ending the COVID-19 pandemic. The letter emphasized that Plaintiffs' priority was for COVID-19 to be eradicated and assured that "we do not intend to file a case asserting patent infringement in the near future" to ensure vaccine development efforts were in no way impacted.

58. Although Pfizer responded a month later stating that it would "reach out in due course," it did not do so, and Genevant did not press the matter at that time in deference to Defendants' important efforts to manufacture and distribute the vaccine. However, having heard nothing for over six months, and with global conditions somewhat improved, Genevant reached out orally and in writing multiple times in the second half of 2021 in an effort to initiate a good faith discussion.

59. On October 12, 2021, Plaintiffs notified Defendants in writing that, in addition to the patents identified in Plaintiffs' November 23, 2020 letter, the manufacture, importation, offer

for sale, sale, and/or use of the Accused Product may also infringe the claims of the '378 Patent, which had issued that same day.

60. On June 3, 2022, Genevant notified Defendants in writing that the manufacture, importation, offer for sale, sale, and/or use of the Accused Product may also infringe the '320 patent, which had issued on April 12, 2022, and the '098 patent, which had issued on May 3, 2022.

H. Defendants Refuse to Compensate Plaintiffs for Using Their Technology

61. Despite Genevant's repeated efforts to discuss reasonable terms for a license, Defendants have refused to take a license from, partner with, or otherwise compensate Plaintiffs for their contribution to Defendants' vaccine. Defendants have also declined to provide product samples to support any assertion that they have not infringed the Asserted Patents. Instead, Defendants continue to infringe the Asserted Patents directly and indirectly, without authority and with actual knowledge of, or willfully blind to, the fact that their actions constitute infringement of the Asserted Patents. On information and belief, Pfizer and BioNTech have at all relevant times been working jointly to coordinate their positions and responses on these matters.

62. Plaintiffs fully support Defendants' efforts to supply vaccines to people in the United States and worldwide and in no way seek to interfere with those efforts. However, Defendants have made extensive use of, and earned billions of dollars in profit exploiting, Arbutus's patented technology, including the technology described and claimed in the Asserted Patents. Defendants' actions have caused harm, and continue to cause harm, to Plaintiffs. Plaintiffs thus have no choice but to defend their proprietary and patented technology and to seek fair and reasonable compensation for the value of their innovation. [15]

[15] The allegations herein are exemplary and without prejudice to Plaintiffs' infringement contentions. In providing these allegations, Plaintiffs do not convey or imply any particular claim constructions or the precise scope of the claims. Plaintiffs' claim construction contentions

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 9,504,651

63. Paragraphs 1 through 62 are incorporated by reference as if fully set forth herein.

64. The United States Patent and Trademark Office duly and legally issued the '651 Patent to one of Arbutus's predecessor companies on November 29, 2016. The '651 Patent is titled "Lipid Compositions for Nucleic Acid Delivery."

65. Arbutus owns, and at all relevant times has owned, the '651 Patent.

66. Genevant holds, and at all relevant times has held, Exclusive Rights in the '651 Patent, including the right to sue and seek damages for the infringement alleged herein.

67. Claims of the '651 Patent cover, among other things, lipid vesicle formulations comprising a plurality of lipid vesicles with mRNA encapsulated in the vesicles.

68. The FDA's December 11, 2020 Emergency Use Authorization letter to Pfizer ("FDA EUA Letter") indicates that the Accused Product contains a nucleoside-modified mRNA encoding the viral spike protein of SARS-CoV-2. The mRNA is encapsulated in lipid particles comprising the following lipids: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol.

69. Defendants have directly infringed and continue to directly infringe the claims of the '651 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, and/or using within the United States, and/or importing into the United States, the Accused Product, incorporating Arbutus's LNP delivery technology covered by the '651 Patent, without authority or license to do so, during the term of the '651 Patent.

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regarding the meaning and scope of the claim terms will be provided under the Court's scheduling order and this District's Local Civil and Patent Rules.

70. For example, Claim 1 of the '651 Patent recites a "lipid vesicle formulation comprising: (a) a plurality of lipid vesicles, wherein each lipid vesicle comprises: a cationic lipid; an amphipathic lipid; and a polyethyleneglycol (PEG)-lipid; and (b) messenger RNA (mRNA), wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles." Claim 9 of the '651 Patent recites "[t]he lipid vesicle formulation of claim 1, wherein each lipid vesicle is a lipid-nucleic acid particle."

71. The Accused Product is a lipid vesicle formulation comprising mRNA and lipid vesicles. The mRNA in the Accused Product encodes the COVID-19 spike protein.

72. The Accused Product comprises a plurality of lipid vesicles wherein each vesicle comprises the following lipids: an ionizable cationic lipid (((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)); an amphipathic lipid (1,2-distearoyl-sn-glycero-3-phosphocholine or "DSPC"); a PEG-lipid (2[(polyethylene glycol)-2000]-N,N ditetradecylacetamide), and cholesterol.

73. Upon information and belief, the Accused Product comprises a lipid vesicle formulation wherein at least 70% of the mRNA in the formulation is fully encapsulated in a plurality of lipid vesicles meeting the requirements of claim 1 of the '651 patent.

74. Defendants have also actively induced infringement of one or more claims of the '651 Patent under 35 U.S.C. § 271(b) because: (i) others, including healthcare professionals, have used the Accused Product by administering it to millions of individuals in the United States, thereby directly infringing one or more claims of the '651 Patent; (ii) Defendants have actively encouraged such other persons, including healthcare professionals, to use the Accused Product by administering it to individuals in the United States; (iii) Defendants intended to cause the directly infringing acts via their active encouragement and such active encouragement has actually led to

the directly infringing acts; and (iv) Defendants, when they committed such acts of encouragement, were aware of the '651 patent and knew that use and administration of the Accused Product would, if performed, infringe one or more claims of the '651 patent. Defendants' acts of inducement are continuing.

75. On information and belief, Defendants have known of the '651 Patent since before they commenced the infringing conduct or have been willfully blind to its existence and contents since then. Upon information and belief, Defendants have long been aware of and actively monitored Arbutus's patent portfolio. BioNTech has been aware of the '651 patent at least as early as 2018 when it entered into a license agreement with Genevant. Pfizer has been aware of the '651 patent (i) as early as the summer of 2018, on information and belief, by virtue of diligence Pfizer conducted in advance of entering into a separate contract with BioNTech, (ii) in early 2020, on information and belief, as part of due diligence Pfizer conducted before agreeing to collaborate with BioNTech on Defendants' vaccine, and (iii) certainly as of November 23, 2020, upon receipt of Plaintiffs' letter to Albert Bourla, DVM, Ph.D., Chairman and CEO of Pfizer, and Doug Lankler, Esq., EVP and General Counsel of Pfizer, with copy to BioNTech, inviting discussions of a license and partnering opportunity, notifying Defendants that they may be infringing the '651 Patent, and providing notice under 35 U.S.C. § 287(a). Despite such knowledge, Defendants have engaged in the manufacture, offer for sale, sale and/or use of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and induced others to infringe the '651 patent, in violation of Plaintiffs' patent rights.

76. Plaintiffs are entitled to a judgment that Defendants infringe the claims of the '651 Patent by engaging in the manufacture, use, sale, and/or offer for sale of the Accused Product

within the United States, and/or the importation of Defendants' vaccine into the United States, and/or by actively inducing others to do the same.

77. Defendants' infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, in the form of a reasonable royalty.

78. Defendants have undertaken their infringing actions despite knowing that such actions infringed one or more claims of the '651 Patent. As such, Defendants have and continue to willfully infringe one or more claims of the '651 Patent.

79. This is an exceptional case. Plaintiffs are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Defendants' infringement of the '651 Patent.

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 8,492,359

80. Paragraphs 1 through 79 are incorporated by reference as if fully set forth herein.

81. The United States Patent and Trademark Office duly and legally issued the '359 Patent to one of Arbutus's predecessor companies on July 23, 2013. The '359 Patent is titled "Lipid Formulations for Nucleic Acid Delivery."

82. Arbutus owns, and at all relevant times has owned, the '359 Patent.

83. Genevant holds, and at all relevant times has held, Exclusive Rights in the '359 Patent, including the right to sue and seek damages for the infringement alleged herein.

84. Claims of the '359 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof.

85. The FDA EUA Letter indicates that the Accused Product is comprised of nucleic acid-lipid particles. The nucleic acid is a nucleoside-modified mRNA encoding the viral spike protein of SARS-CoV-2. The mRNA is encapsulated in lipid particles comprising the following lipids: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2[(polyethylene

glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol. The FDA EUA Letter also provides nominal weights for each of the lipid components.

86. Defendants have directly infringed and continue to directly infringe claims of the '359 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, and/or using within the United States, and/or importing into the United States, the Accused Product incorporating Arbutus's LNP delivery technology covered by the '359 Patent, without authority or license to do so, during the term of the '359 Patent.

87. For example, Claim 1 of the '359 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle."

88. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

89. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: a cationic lipid having a protonatable tertiary amine (((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)); a mixture of the non-cationic lipids phospholipid (1,2-distearoyl-sn-glycero-3-phosphocholine or "DSPC") and cholesterol; and a

PEG-lipid conjugate, 2[(polyethylene glycol)-2000]-N,N ditetradecylacetamide, that inhibits aggregation of particles.

90. On information and belief, the Accused Product comprises nucleic acid-lipid particles comprising (a) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (b) DSPC comprising from 3 mol % to 15 mol % of the total lipid present in the particle; (c) the cholesterol in the amount of 30 mol % to 40 mol % of the total lipid present in the particle; and (c) a PEG-lipid conjugate consisting of from 0.5 mol % to 2 mol % of the total lipid present in the particle.

91. Defendants have also actively induced infringement of one or more claims of the ’359 Patent under 35 U.S.C. § 271(b) because: (i) others, including healthcare professionals, have used the Accused Product by administering it to millions of individuals in the United States, thereby directly infringing one or more claims of the ’359 Patent, (ii) Defendants have actively encouraged such other persons, including healthcare professionals, to use the Accused Product by administering it to individuals in the United States, (iii) Defendants intended to cause the directly infringing acts via their active encouragement and such active encouragement has actually led to the directly infringing acts, and (iv) Defendants, when they committed such acts of encouragement, were aware of the ’359 Patent and knew that use and administration of the Accused Product would, if performed, infringe one or more claims of the ’359 Patent. Defendants’ acts of inducement are continuing.

92. On information and belief, Defendants have known of the ’359 Patent since before they commenced the infringing conduct or have been willfully blind to its existence and contents since then. Upon information and belief, Defendants have long been aware of and actively monitored Arbutus’s patent portfolio. BioNTech has been aware of the ’359 patent at least as early

as 2018 when it entered into a license agreement with Genevant. Pfizer has been aware of the '359 patent (i) as early as the summer of 2018, on information and belief, by virtue of diligence Pfizer conducted in advance of entering into a separate contract with BioNTech, (ii) in early 2020, on information and belief, as part of due diligence Pfizer conducted before agreeing to collaborate with BioNTech on Defendants' vaccine, and (iii) certainly as of November 23, 2020, upon receipt of Plaintiffs' letter to Albert Bourla, DVM, Ph.D., Chairman and CEO of Pfizer, and Doug Lankler, Esq., EVP and General Counsel of Pfizer, with copy to BioNTech, inviting discussions of a license and partnering opportunity, notifying Defendants that they may be infringing the '359 Patent, and providing notice under 35 U.S.C. § 287(a). Despite such knowledge, Defendants have engaged in the manufacture, offer for sale, sale, and/or use of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and induced others to infringe the '359 patent, in violation of Plaintiffs' patent rights.

93. Despite such knowledge, Defendants have engaged in the unlicensed manufacture, offer for sale, sale and/or use of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, in violation of Plaintiffs' patent rights.

94. Plaintiffs are entitled to a judgment that Defendants infringe the claims of the '359 Patent by engaging in the manufacture, use, sale, and/or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same.

95. Defendants' infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, in the form of a reasonable royalty.

96. Defendants have undertaken their infringing actions despite knowing that such actions infringe one or more claims of the ’359 Patent. As such, Defendants have and continue to willfully infringe one or more claims of the ’359 Patent.

97. This is an exceptional case. Plaintiffs are entitled to attorneys’ fees and costs under 35 U.S.C. § 285 as a result of Defendants’ infringement of the ’359 Patent.

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 11,141,378

98. Paragraphs 1 through 97 are incorporated by reference as if fully set forth herein.

99. The United States Patent and Trademark Office duly and legally issued the ’378 Patent to Arbutus on October 12, 2021. The ’378 Patent is titled “Lipid Formulations for Nucleic Acid Delivery.”

100. Arbutus owns, and at all relevant times has owned, the ’378 Patent.

101. Genevant holds, and at all relevant times has held, Exclusive Rights in the ’378 Patent, including the right to sue and seek damages for the infringement alleged herein.

102. On the date that the ‘378 Patent was issued, Plaintiffs sent Defendants written notice that Defendants may be infringing one or more claims of the ’378 Patent and noted ongoing licensing discussions.

103. Claims of the ’378 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof.

104. The FDA EUA Letter indicates that the Accused Product is comprised of nucleic acid-lipid particles. The nucleic acid is a nucleoside-modified mRNA encoding the viral spike protein of SARS-CoV-2. The mRNA is encapsulated in lipid particles comprising the following lipids: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol. The FDA EUA Letter also provides nominal weights for each of the lipid components.

105. Defendants have directly infringed and continue to directly infringe claims of the '378 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, and/or using within the United States, and/or importing into the United States, the Accused Product incorporating Arbutus's LNP delivery technology covered by the '378 Patent, without authority or license to do so, during the term of the '378 Patent.

106. For example, Claim 1 of the '378 Patent recites a "nucleic acid-lipid particle consisting essentially of: (a) an RNA; (b) a cationic lipid having a protonatable tertiary amine; (c) a mixture of a phospholipid and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle, wherein the phospholipid consists of from 3 mol % to 15 mol % of the total lipid present in the particle; and (d) a polyethyleneglycol (PEG)-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle."

107. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

108. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: a cationic lipid having a protonatable tertiary amine (((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)); a mixture of a phospholipid (1,2-distearoyl-sn-glycero-3-phosphocholine or "DSPC") and cholesterol; and a PEG-lipid conjugate, 2[(polyethylene glycol)-2000]-N,N ditetradecylacetamide.

109. On information and belief, the Accused Product comprises nucleic acid-lipid particles comprising (a) a cationic lipid having a protonatable tertiary amine; (b) a mixture of a DSPC and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle, wherein the DSPC consists of from 3 mol % to 15 mol % of the total lipid present in the particle;

and (c) a PEG-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle.

110. Defendants have also actively induced infringement of one or more claims of the '378 Patent under 35 U.S.C. § 271(b) because: (i) others, including healthcare professionals, have used the Accused Product by administering it to millions of individuals in the United States, thereby directly infringing one or more claims of the '378 Patent, (ii) Defendants have actively encouraged such other persons, including healthcare professionals, to use the Accused Product by administering it to individuals in the United States, (iii) Defendants intended to cause the directly infringing acts via their active encouragement and such active encouragement has actually led to the directly infringing acts, and (iv) Defendants, when they committed such acts of encouragement, were aware of the '378 Patent and knew that use and administration of the Accused Product would, if performed, infringe one or more claims of the '378 Patent. Defendants' acts of inducement are continuing.

111. Despite such knowledge, Defendants have engaged in the unlicensed manufacture, offer for sale, sale, and/or use of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, in violation of Plaintiffs' patent rights.

112. Plaintiffs are entitled to a judgment that Defendants infringe the claims of the '378 Patent by engaging in the manufacture, use, sale, and/or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same.

113. Defendants' infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, in the form of a reasonable royalty.

114. Defendants have undertaken their infringing actions despite knowing that such actions infringe one or more claims of the '378 Patent. As such, Defendants have and continue to willfully infringe one or more claims of the '378 Patent.

115. This is an exceptional case. Plaintiffs are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Defendants' infringement of the '378 Patent.

COUNT 4: INFRINGEMENT OF U.S. PATENT NO. 11,298,320

116. Paragraphs 1 through 115 are incorporated by reference as if fully set forth herein.

117. The United States Patent and Trademark Office duly and legally issued the '320 Patent to Arbutus on April 12, 2022. The '320 Patent is titled "Liposomal Apparatus and Manufacturing Methods."

118. Arbutus owns, and at all relevant times has owned, the '320 Patent.

119. Genevant holds, and at all relevant times has held, Exclusive Rights in the '320 Patent, including the right to sue and seek damages for the infringement alleged herein.

120. Claims of the '320 Patent cover, among other things, an apparatus for producing lipid vesicles encapsulating a nucleic acid within the lipid vesicle.

121. Defendants have directly infringed and continue to directly infringe claims of the '320 Patent under 35 U.S.C. § 271(a) by using the patented apparatus covered by the '320 Patent to make the Accused Product in the United States, without authority or license to do so, during the term of the '320 Patent.

122. For example, Claim 1 of the '320 Patent recites "an apparatus for producing a lipid vesicle encapsulating a nucleic acid within the lipid vesicle, the apparatus comprising: a first reservoir containing an aqueous solution including a nucleic acid; a second reservoir containing an organic lipid solution, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v; and a pump mechanism

configured to pump the aqueous solution and the organic lipid solution into a mixing chamber at different flow rates relative to each other; wherein the mixing chamber is configured such that the aqueous solution and the organic lipid solution are introduced into the mixing chamber as opposing flows at about 180º relative to each other and mixed within the mixing chamber to instantaneously produce a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution."

123. The Accused Product includes a lipid vesicle encapsulating a nucleic acid. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

124. The Accused Product is manufactured using an apparatus with: a first reservoir containing an aqueous solution including a nucleic acid; a second reservoir containing an organic lipid solution; a pump mechanism configured to pump the aqueous solution and the organic lipid solution into a mixing chamber at different flow rates relative to each other; and the mixing chamber is configured such that the aqueous solution and the organic lipid solution are introduced into the mixing chamber as opposing flows at about 180º relative to each other and mixed within the mixing chamber to instantaneously produce a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution.

125. For example, in his recently published book, Pfizer CEO Dr. Bourla describes the manufacturing of the Accused Product with an apparatus that meets the above-recited limitations. He confirms that the apparatus used to make the Accused Product employs "high pressure pumps" for pumping "aqueous materials" (thus from a first reservoir containing an aqueous solution including a nucleic acid) and "organic streams" (thus from a second reservoir containing an organic lipid solution). Opposing steams of the aqueous solution and the organic solution are mixed in a

"T-mixer" with "internal geometry that enables the formation to combine into the lipid nanoparticle." In order to scale production they "replicated the pumps and T-mixers dozens and dozens of times into lipid nanoparticle skids" similar to a "warehouse-sized data center with hundreds and hundreds of racks of network computers," only here with hundreds and hundreds of lipid nanoparticle skids.[16]

126. On information and belief, the "T-mixer" used in the manufacturing process is shown below. This image is a screen grab from a CNN interview of Mike McDermott, Pfizer's President of Global Supply, during which Mr. McDermott gave a tour of a Pfizer US-based production facility and explained how the T-mixer is used to create LNPs.[17]

[16] Albert Bourla, *MOONSHOT: INSIDE PFIZER'S NINE-MONTH RACE TO MAKE THE IMPOSSIBLE POSSIBLE* (2022) at 91.

[17] CNN, "Take an exclusive look inside a busy Covid-19 vaccine facility"(www.cnn.com/videos/health/2021/03/31/pfizer-vaccine-manufacturing-exclusive-gupta-vpx.cnn).

127. As shown in the below image, also from the CNN interview, the T-mixer is a mixing chamber configured to create opposing flows of the aqueous (blue) and lipid (yellow) solutions at about 180º relative to each other and at different flow rates relative to each other.

128. On information and belief, the apparatus for making the Accused Product has a second reservoir containing an organic lipid solution wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v.

129. The ’320 Patent issued on April 12, 2022. On June 3, 2022, Genevant notified Defendants in writing that the manufacture of the Accused Product may infringe the ’320 Patent.

130. Despite such knowledge, Defendants nonetheless have engaged in the manufacture of the Accused Product using an apparatus as claimed in the ’320 Patent within the United States, in violation of Plaintiffs’ patent rights.

131. Arbutus and Genevant are entitled to a judgment that Defendants infringe the claims of the '320 Patent by engaging in the manufacture, use, sale, and/or offer for sale of the Accused Product within the United States, using an apparatus as claimed in the '320 Patent.

132. Defendants' infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, in the form of a reasonable royalty.

133. Defendants have undertaken their infringing actions despite knowing that such actions infringe one or more claims of the '320 Patent. As such, Defendants have and continue to willfully infringe one or more claims of the '320 Patent.

134. This is an exceptional case. Plaintiffs are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Defendants' infringement of the '320 Patent.

COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 11,318,098

135. Paragraphs 1 through 134 are incorporated by reference as if fully set forth herein.

136. The United States Patent and Trademark Office duly and legally issued the '098 Patent to Arbutus on May 3, 2022. The '098 Patent is titled "Liposomal Apparatus and Manufacturing Methods."

137. Arbutus owns, and at all relevant times has owned, the '098 Patent.

138. Genevant holds, and at all relevant times has held, Exclusive Rights in the '098 Patent, including the right to sue and seek damages for the infringement alleged herein.

139. Claims of the '098 Patent cover, among other things, processes for producing lipid vesicles encapsulating a nucleic acid within the lipid vesicle.

140. Defendants have directly infringed and continue to directly infringe claims of the '098 Patent under 35 U.S.C. § 271(a) by manufacturing the Accused Product using the process claimed in one or more claims of the '098 Patent, without authority or license to do so, during the term of the '098 Patent.

141. For example, Claim 1 of the ’098 Patent recites “[a] process for producing a lipid vesicle encapsulating a nucleic acid within the lipid vesicle, the process comprising: providing an aqueous solution including a nucleic acid in a first reservoir; providing an organic lipid solution in a second reservoir, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v; introducing the aqueous solution and the organic lipid solution into a mixing chamber as opposing flows at about l80° relative to each other and at different flow rates relative to each other; and mixing the organic lipid solution with the aqueous solution, wherein the mixing instantaneously produces a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution.”

142. Pfizer, itself and through its subsidiary companies, has performed each step of one or more of the method claims of the ’098 Patent in the United States in its manufacturing facilities. Pfizer performs each step of one or more method claims of the ’098 Patent in the United States on its own behalf and on behalf of BioNTech.

143. The Accused Product includes a lipid vesicle encapsulating a nucleic acid. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

144. The Accused Product is manufactured via a process for producing a lipid vesicle encapsulating a nucleic acid within the lipid vesicle, the process comprising: providing an aqueous solution including a nucleic acid in a first reservoir; providing an organic lipid solution in a second reservoir, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol; introducing the aqueous solution and the organic lipid solution into a mixing chamber as opposing flows at about l80° relative to each other and at different flow rates relative to each other; and mixing the organic lipid solution with the aqueous solution, wherein the mixing instantaneously

produces a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution.

145. For example, in his recently published book, Pfizer CEO Dr. Bourla describes the Defendants' manufacturing of the Accused Product via a process that meets the above-recited limitations. He confirms that Defendants' "high pressure pumps" that pump "aqueous materials" (thus from a first reservoir containing an aqueous solution including a nucleic acid) and "organic streams" (thus from a second reservoir containing an organic lipid solution). Opposing steams of the aqueous solution and the organic solution are mixed in a "T-mixer" with "internal geometry that enables the formation to combine into the lipid nanoparticle." To scale production, Defendants "replicated the pumps and T-mixers dozens and dozens of times into lipid nanoparticle skids" similar to a "warehouse-sized data center with hundreds and hundreds of racks of network computers," only here with hundreds and hundreds of lipid nanoparticle skids.[18]

146. As shown in the images above (*see supra* ¶¶ 126-127), the T-mixer is a mixing chamber used to create opposing flows of the aqueous (blue) and lipid (yellow) solutions at about 180º relative to each other and at different flow rates relative to each other.

147. On information and belief, in the process for making the Accused Product Defendants provide a second reservoir containing an organic lipid solution wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v.

148. The '098 Patent issued on May 3, 2022. On June 3, 2022, Genevant notified Defendants in writing that the manufacture of the Accused Product may infringe the '098 patent.

[18] Albert Bourla, *MOONSHOT: INSIDE PFIZER'S NINE-MONTH RACE TO MAKE THE IMPOSSIBLE POSSIBLE* (2022) at 91.

149. Despite such knowledge, Defendants have engaged in the manufacture of the Accused Product via a process as claimed in one or more claims of the '098 Patent within the United States, in violation of Plaintiffs' patent rights.

150. Arbutus and Genevant are entitled to a judgment that Defendants infringe the claims of the '098 Patent by engaging in the manufacture of the Accused Product within the United States.

151. Defendants' infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, in the form of a reasonable royalty.

152. Defendants have undertaken their infringing actions despite knowing that such actions infringe one or more claims of the '098 Patent. As such, Defendants have and continue to willfully infringe one or more claims of the '098 Patent.

153. This is an exceptional case. Plaintiffs are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Defendants' infringement of the '098 Patent.

PRAYER FOR RELIEF

WHEREFORE, Arbutus and Genevant respectfully request that this Court enter judgment in their favor against Pfizer and BioNTech and grant the following relief:

a. A judgment that Pfizer has infringed or will infringe each of the Asserted Patents under 35 U.S.C. § 271(a) or (b) by making, offering to sell, selling, and/or using within the United States, and/or importing into the United States, the Accused Product, or actively inducing others to do the same, during the term of each Asserted Patent;

b. A judgment that BioNTech has infringed or will infringe each of the Asserted Patents under 35 U.S.C. § 271(a) or (b) by making, offering to sell, selling, and/or using within the United States, and/or importing into the United States, the Accused Product, or actively inducing others to do the same, during the term of each Asserted Patent;

c. An award of damages sufficient to compensate Arbutus and Genevant for Defendants' infringement under 35 U.S.C. § 284, in the form of a reasonable royalty on all infringing sales or other dispositions of Accused Product;

d. A judgment that the infringement has been willful and an enhancement of damages;

e. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

f. An award of Arbutus's and Genevant's costs and expenses in this action;

g. An award of pre- and post-judgement interest; and

h. Such other and further relief as this Court may deem just and proper.

JURY DEMAND

Arbutus and Genevant, by and through undersigned counsel, hereby demand, pursuant to Federal Rule of Civil Procedure 38, a trial by jury on all claims so triable in this action.

Dated: April 4, 2023

Respectfully submitted,

OF COUNSEL:

Attorneys for Plaintiff Genevant Sciences GmbH

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Plaintiffs Arbutus Biopharma Corporation & Genevant Sciences GmbH hereby certify that this matter in controversy is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: April 4, 2023

Respectfully submitted,

Attorneys for Plaintiffs Arbutus Biopharma Corp. & Genevant Sciences GmbH

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LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Plaintiffs Arbutus Biopharma Corporation & Genevant Sciences GmbH hereby certify that they seek both monetary damages greater than $150,000, and therefore this action is not appropriate for compulsory arbitration.

Dated: April 4, 2023

Respectfully submitted,

Attorneys for Plaintiffs Arbutus Biopharma Corp. & Genevant Sciences GmbH

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